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**Attorney Docket No.: P-4921-US**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| Applicant(s): | BODINE, Peter Van Nest et al. | Examiner: | Not yet known |
| Serial No.: | 10/642,503 | Group Art Unit: | Not yet known |
| Filed: | August 18, 2003 | | |
| Title: | BMP-2 ESTROGEN RESPONSIVE ELEMENT AND METHODS OF USING THE SAME | | |

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §§1.56, 1.97 and 1.98, this Information Disclosure Statement includes Form PTO-1449:

1. ☒ listing documents including patents, publications and other information for consideration by the Examiner, however, since the subject application was filed after June 30, 2003, copies of United States patents, and/or United States patent applications, and/or United States patent application publications are not included in this information disclosure statement; and/or
2. ☐ listing documents including patents, publications and other information that have been previously cited or submitted to the Patent Office in prior application U.S. Serial No. _____, filed _____ which is properly identified and relied on for an earlier effective filing date under 35 U.S.C. 120 for consideration by the Examiner; however, in accordance with 37 C.F.R. 1.98(d), copies of such documents are not included in this information disclosure statement; and/or
3. ☐ listing documents including patents, publications, and other information for consideration by the Examiner, copies of which are included with this information disclosure statement;

4. ☐ listing other information for the Examiner's consideration which was cited in a communication from a foreign patent office in a counterpart foreign application, a copy of which is included with this information disclosure statement.

The information herein cited is only in fulfillment of Applicant(s) duty of candor in disclosing all information brought to Applicant(s) attention. This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art". If it should be determined that any of the listed documents do not constitute "prior art" under United States law, Applicant(s) reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant(s) further reserve(s) the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each and every document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO-1449) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application and is evidence that the Examiner has considered the document.

This Information Disclosure Statement is being filed:

**I)** ☒ Within three (3) months of filing the subject Application or entry of the subject Application into the national stage or before mailing of the first Office Action on the merits of the subject Application or a request for continued examination thereof, whichever event occurs last pursuant to of 37 C.F.R §1.97 (b); or

**II)** ☐ After the period specified in (I) but before the mailing date of either a final Official Action under 37 C.F.R §1.113 or a notice of allowance under 37 C.F.R §1.311 whichever occurs first and;

1. ☐ the undersigned hereby states that each item of information listed on the Form PTO-1449 was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to

the filing of this Information Disclosure Statement or (ii) not cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, not known to any individual designated in §1.56(c) more than three (3) months prior to the filing of this information disclosure statement; or

2. ☐ the undersigned hereby authorizes the Patent Office to charge the fee in the amount of $180.00 under 37 C.F.R §1.17 (p) to Deposit Account 05-0649.

**III)** ☐ After the period in (I) and (II) but before the payment of the issue fee and,

1. The undersigned hereby states:

a) ☐ that each item of information cited on the form PTO-1449 was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three (3) months prior to the filing of this Information Disclosure Statement; or

b) ☐ that no items of information contained in Form PTO-1449 was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; and

2. ☐ The undersigned hereby authorizes the Patent Office to charge the Petition fee in the Amount of $180.00 under 37 C.F.R §1.17 (p) to Deposit Account 05-0649.

**Except** for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 05-0649.

Respectfully submitted,

Mark S. Cohen
Attorney for Applicant(s)
Registration No. 42,425

Dated: July 25, 2004

**Eitan, Pearl, Latzer & Cohen Zedek, LLP.**
10 Rockefeller Plaza, Suite 1001
New York, New York 10020
Tel: (212) 632-3480
Fax: (212) 632-3490

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Substitute for form 1449A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

*(use as many sheets as necessary)*

Sheet 1 of 4

| Complete if Known | |
|---|---|
| Application Number | 10/642,503 |
| Filing Date | August 18, 2003 |
| First Named Inventor | BODINE, Peter Van Nest |
| Group Art Unit | Not yet known |
| Examiner Name | Not yet known |
| Attorney Docket Number | P-4921-US |

## U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No.[1] | U.S. Patent Document Number | Kind Code[2] (if known) | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|---|---|---|---|---|---|---|
| | A | 4,665,018 | | Vold, Barbara S. | May 12, 1987 | |
| | B | 4,736,866 | | Leder, et al | April 12, 1998 | |
| | C | 4,870,009 | | Evens, et al | September 26, 1989 | |
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## FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No.[1] | Foreign Patent Document Office[3] | Number[4] | Kind Code[5] (if known) | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T[6] |
|---|---|---|---|---|---|---|---|---|
| | D | | 2004016639 | WO | Bodine, Peter van Nest et al | February 26, 2004 | | ☐ |
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| Examiner Signature | | Date Considered | |
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[1] Unique citation designation number. [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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|---|---|---|---|---|---|
| | | | | **Application Number** | **10/642,503** |
| **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** | | | | **Filing Date** | **August 18, 2003** |
| | | | | **First Named Inventor** | **BODINE, Peter Van Nest** |
| | | | | Group Art Unit | **Not yet known** |
| *(use as many sheets as necessary)* | | | | Examiner Name | **Not yet known** |
| Sheet | 2 | of | 4 | Attorney Docket Number | **P-4921-US** |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---|---|---|---|
| Examiner Initials* | Cite No.[1] | Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T[2] |
| | E | Black, LJ et al., (1994) Raloxifene (LY139481 HCl) Prevents Bone Loss and Reduces Serum Cholesterol without Causing Uterine Hypertrophy in Ovariectomized rats. J. Clin. Invest. 93(1): 63-69. | ☐ |
| | F | Chowdhury, J. R. et al. (1991) Long-Term Improvement of Hypercholesterolemia After ex Vivo Gene Therapy in LDLR-Deficient Rabbits. Science 254:1802-1805. | ☐ |
| | G | Clemett D. et al., (2000) Raloxifene – Review of its Use in Postmenopausal Osteoporosis. Drugs 60(2):379-411 | ☐ |
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| | L | Kay, M. A. et al. (1992) Hepatic Gene Therapy: Persistent Expression of Human-α1-Antitrypsin in Mice after Direct Gene Delivery In Vivo. Human Gene Therapy 3:641-647. | ☐ |
| | M | Oreffo R et al. (1999) Expression of estrogen receptor-alpha in cells of the osteoclastic lineage. Histochem Cell Biol 111: 125-33. | ☐ |
| | N | Rosen V et al., (1996) Signaling Pathways in Skeletal Formation: A Role for BMP Receptors. Ann N Y Acad Sci. 785: 59-69 | ☐ |
| | O | Rosenfeld, M. A. et al. (1992) In Vivo Transfer of the Human Cystic Fibrosis Transmembrane Conductance regulator Gene to the Airway Epithelium. Cell 68:143-155. | ☐ |
| | P | Wells, G. et al (2002) V. Meta-Analysis of the Efficacy of Hormone Replacement Therapy in Treating and Preventing Osteoporosis in Postmenopausal Women. Endocrine Reviews 23 (4):529-539. | |
| | Q | Sato M. et al., (1996) Raloxifene, tamoxifen, nafoxidine, or estrogen effects on reproductive3 and nonreproductive tissues in ovariectomized rates. FASEB Journal. 10(8): 905-912. | ☐ |
| | R | Wall, R. J. et al. (1992) Making transgenic livestock: Genetic Engineering on a Large Scale. J. Cell. Biochem. 49: 113-120 | ☐ |
| | S | Wang EA et al., (1993) Bone Morphogenetic Proten-2 Causes Commitment and Differentiation in C3H10T1/2 and 3T3 Cells. Growth Factors 9:57-71. | ☐ |
| | T | Wilson, J. M et al. (1988) Retrovirus-mediated transduction of adult hepatocytes. Proc. Natl. Acad. Sci. USA 85:3014-3018. | ☐ |

| Examiner Signature | | Date Considered | |
|---|---|---|---|

* **EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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| Substitute for form 1449B/PTO | *Complete if Known* | |
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| | **Filing Date** | **August 18, 2003** |
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| | Group Art Unit | **Not yet Known** |
| *(use as many sheets as necessary)* | Examiner Name | **Not yet Known** |
| Sheet 3 of 4 | Attorney Docket Number | **P-4921-US** |

**NON PATENT LITERATURE DOCUMENTS**

| Examiner Initials* | Cite No.[1] | Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T[2] |
|---|---|---|---|
| | U | Wolff, J. A. et al. (1990) Direct Gene Transfer into Mouse Muscle in Vivo. Science 247:1465-1468. | ☐ |
| | V | Wozney JM et al., (1988) Novel Regulators of Bone Formation: Molecular Clones and Activities. Science 242:1528-1534. | ☐ |
| | W | Wozney JM et al., (1998) Bone Morphogenetic Protein and Bone Morphogenetic Protein Gene Family in Bone Formation and Repair. Clin Orthop 346:26-37. | ☐ |
| | X | Yang NN et al., (1996) Identification of an Estrogen Response Element Activated by Metabolites of 17β-Estradiol and Raloxifene. Science 273:1222-1225. | ☐ |
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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 4

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| Filing Date | August 18, 2003 |
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## NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No.[1] | Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T[2] |
|---|---|---|---|
| | AK | Ferry N et al (1991) Retroviral-mediated gene transfer into hepatocytes in vivo. Proc Natl Acad Sci U S A. 88(19):8377-81. | ☐ |
| | AL | Wilson J et al (1992) A Novel Mechanism for Achieving Transgene Persistence in vivo after somatic Gene Transfer into Hepatocytes. J Biol Chem 267(16):11483-9 | ☐ |
| | AM | Quantin B et al (1992) Adenovirus as an expression vector in muscle cells in vivo. Proc Natl Acad Sci U S A 89(7):2581-4. | ☐ |
| | AN | Dai Y et al (1992) Gene therapy via primary myoblasts: Long-terms expression of factor IX protein following transplatation in vivo. Proc Natl Acad Sci U S A. 89(22):10892-5. | ☐ |
| | AO | Van Beusechem et al (1992) Long-term expression of human adenosine deaminase in rhesus monkeys transplanted with retrovirus-infected bone-marrow cells. Proc Natl Acad Sci U S A. 89(16):7640-4. | ☐ |
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| | AV | Zhou H et al (1993) Estrogens Activate Bone Morphogenetic Protein-2 Gene transcription in Mouse Mesenchymal Stem Cells. Mol Endocrinology 17: 56-66. | ☐ |
| | AW | Orly J et al (1994) Tyrosine Kinase Inhibitor AG18 arrests follicle-stimulating Hormone-induced granulose cell differentiation: Use of reverse transcriptase-polymerase chain reaction assay for multiple messenger ribonucleic acids. Endocrinology 134: 2336-46. | ☐ |
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| | BA | Garrett I et al, (2001) Statins and Bone Formation. Current Pharmaceutical Design 7: 715-36. | |

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